REMARKS

Applicants respectfully request entry of the foregoing amendments, re-examination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112.

As noted in the Office Action Summary, Claims 2, 3, 5-12, 20, 22-25, 27-41, 54-62, and 64-67 are pending in the above-identified application. Claims 1, 4, 13-19, 21, 26, 42-53, and 63 were previously canceled. Claim 7 is independent.

Applicants have amended claims 2, 5-8, 11-12, 28, 31-32, 37-38, 54, 57, and 64. Applicants have introduced new claim 68. Support for the claim amendments and new claim can be found at least in the original claims as filed and at least at pages 6-11 of the specification.

Applicants further note that on page 15 of the Office Action, the Office has remarked that the claims are free of the art.

1. Sequence Listing

The CRF and paper sequence listing submitted August 10, 2000 has been entered into the record. The Office objects to the Sequence Listing as not complying with 37 C.F.R. § 1.821(c), which requires that each sequence must appear as separate sequences. Specifically, nucleotide sequences are identified by SEQ ID NOS: 1-6. However, the Office asserts that the protein sequences are not separately listed. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821 through 1.825.

Applicants submit herewith a Substitute Sequence Listing introducing new sequence identifiers 32-40. SEQ ID NOS: 32-37 correspond respectively to nucleic acids SEQ ID NOS: 1-6. Applicants have amended the specification at pages 6, 8, and 26 to update the recitation of the new sequence identifiers. The amendment to the claims and specification thereby moots the objection. Applicants also have amended the specification at pages 40, 42, and 45 for the peptide sequences corresponding to nucleic acids SEQ ID NOS: 27, 29, and 31; the sequence identifiers for the peptides are SEQ ID NOS: 38-40, which correspond respectively to nucleic acid SEQ ID NOS: 27, 29, and 31.

Claims 2-3 and 5-6 are objected to for failing to further limit parent claim 7, "because SEQ ID NO: 22 encoding 21 is not specific to the aromatic acyltransferase of the invention,

therefore the sequence further broadens the scope of the polynucleotide." Applicants disagree with the Office's assertion. Claims 2-3 and 5-6 each recite a specific sequence as well as other characteristics, such that each claim further limits claim 7. Applicants respectfully request withdrawal of the objection inv view of the arguments.

2. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 2-3, 5-12, 20, 22-25, 27-41, 54-62, and 64-67 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, Claims 7-8, 28 and 54 (and the claims dependent thereon) were rejected for reciting DNA sequences rather than amino acid sequences. Applicants have amended the claims and provided a substitute Sequence Listing, wherein the polypeptides which are encoded by SEQ ID NOS: 1-6 are respectively presented in SEQ ID NOS: 32-37. Accordingly, in view of the amendments to the claims, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Claim 8 also stands rejected for referring to canceled claim 1. Applicants have amended claim 8 to refer to claim 7. Accordingly, Applicants respectfully request withdrawal of the rejection in view of the amendment to the claim. Applicants further request allowance of claim 8.

Claims 5-8 and 28 stand rejected as indefinite for the use of functional language. While Applicants disagree with the Office's assertion of indefinite use of functional language, Applicants have amended claims 5-8. In view of the claims now being dependent from claim 7, Applicants assert that claims 5-8 are definite. Accordingly, Applicants respectfully request withdrawal of the rejection as to claims 5-8, and allowance of the claims.

The Office asserts that flavonoids and anthocyanin are used interchangeably in claims 5-8 and 28. The amendments to claims 5-8 set forth the subject matter contained therein more clearly. Applicants respectfully disagree with regard to claim 28. Applicants assert that flavonoid and anthocyanin are not used interchangeably within claim 28. Thus, the basis for rejection appears unclear and should respectfully be withdrawn.

Claim 2 further stands rejected as indefinite for "the recitation of "using" without positive method steps delimiting how this use is actually practiced." Applicants have amended claim 2 to no longer recite "using". Accordingly, the rejection for indefiniteness should be withdrawn and the claim allowed.

Claims 11-12, 31-32, and 57 stand rejected for lack of antecedent basis for the term "said host". Applicants have taken the Examiner's suggested and amended claims 11-12, 31-32, and 57 to recite "said host cell". In view of the amendment to the claims, Applicants respectfully request withdrawal of the rejection and allowance of claims 11-12, 31-32, and 57.

Claims 11 and 31 also stand rejected for recitation of "microbial" for alleged lack of proper Markush language. Applicants have amended the claims as suggested by the Examiner, thereby mooting the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Claims 12 and 32 stand rejected as indefinite for recitation of the term "plant body". Without acquiescing as to the meaning of the term, Applicants have amended the claims such that the claims no longer recite the term, thereby mooting the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Claim 37 stands rejected as indefinite, because "flower" is an organ rather than a tissue. Applicants have amended the claims such that it no longer recites "tissue is a flower", thereby mooting the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claim.

Claim 38 stands rejected as indefinite with the recitation of "the same property", "because it is unclear what property is being referred to." Office Action, page 6. Applicants have amended the claims such that it no longer recites "the same property", thereby mooting the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claim.

3. Claim Rejections – 35 U.S.C. § 101

Claims 38 and 64 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to a non-statutory subject matter. The Office alleges that the "claimed cutflower is indistinguishable from the flower of a naturally growing plant."

Applicants have amended the claims to recite "wherein the color of said flower's has been altered by introducing said polynucleotide into said plant". The introduction of the polynucleotide into the plant, and thereby the flower, would distinguish the cut flower from a naturally growing plant. Accordingly, the rejection under 35 U.S.C. § 101 has been obviated, and the rejection should respectfully be withdrawn and the claims allowed.

4. Claim Rejections – 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 2-3, 5-12, 20, 22-25, and 27-41 remain rejected under 35 U.S.C. § 112, first paragraph. The Office admits that the specification is enabling for claims limited to the isolated polynucleotide of SEQ ID NO: 1-6, a vector, plant cell/tissue/cut flower, microbial cell, plant comprising it, and a method of transforming a plant with said vectors. However, the Office alleges that the broader scope claimed is not enabled.

Applicants traverse the rejection. Applicants first note that Claims 7 and 8 have been amended to recite SEQ ID NOS: 32 to 37, which are the polypeptides encoded by SEQ ID NOS: 1-6 respectively.

Applicants point out that ***no*** working examples are necessary in any specification for the claims of that specification to be patentable. M.P.E.P. § 2164.02 and *Training Materials for Examining Patent Applications With Respect to 35 U.S.C. Section 112, First Paragraph – Enablement Chemical/Biotechnical Applications*, page 27. Here, Applicants provide 6 examples of polynucleotides encoding acyltransferases from different plant species. Yet, the Office asserts that this is insufficient to claim the broader genus of acyltransferaces. Applicants assert that "[p]roof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." *Training Materials for Examining Patent Applications With Respect to 35 U.S.C. Section 112, First Paragraph – Enablement Chemical/Biotechnical Applications*, page 29. "The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole." Presentation by SPE Remy Yucel entitled "35 U.S.C. § 112, first paragraph and the Wands Analysis" of June 15, 2005. Applicants assert that the Office has not proffered adequate reasons to establish that the skilled person at the time could not have used the genus as a whole absent undue experimentation. Applicants respectfully note that a great deal of experimentation may be required and still not be considered undue. Thus, Applicants submit that a *prima facie* case of lack of enablement has not been adduced.

Further, the Office asserts that the use of SEQ ID NOS: 21 and 22 as probes is not sufficient because these probes could allegedly detect polynucleotides which do not encode polypeptides with acyltransferase activity. Applicants point out that the specifications and its teachings must be viewed ***as a whole*** and not picked apart piecemeal with each piece viewed in isolation (*See* M.P.E.P. § 2164.02: "To make a valid rejection, one must evaluate all the

facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims."). *See also*, M.P.E.P. § 2164.05. The allegation that SEQ ID NOS: 21 and 22 could detect sequences encoding proteins that are not acyltransferace does negate the ability at the time of the skilled artisan to recognize polypeptides with acyltransferace activity from those without. In fact, these probes were used to identify and isolate and acyltransferace from perillas (Example 11, pages 34-37). Accordingly, the Office's allegation does not support a *prima facie* case of lack of enablement as to claims 2 and 2. Therefore, the rejection should be withdrawn and the claims allowed.

The Office cites to *Genentech Inc. v. Novo Nordisk A/S* and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd* on page 12 in support of its position. Regarding *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997), this case is distinguishable from the instant facts on several grounds. First, the *Genentech* case is directed to events which took place in 1979 (the priority date of the first filed application which later issued in 1986 as U.S. Patent No. 4,601,980), which is more than 15 years prior to the events of the instant application. Additionally, in *Genentech*, only examples relating to a species of human growth hormone were provided. In the instant case, Applicants have provided examples of acyltransferases from several species. Applicants further note that at the time of the *Genentech* case, PCR was not a developed technology. At the time of this application, PCR was a developed technology. The findings of *Genentech* therefore are distinguishable from the instant facts and claims, and do not support the Office's position.

Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 U.S.P.Q.2d 1016, 1027 (Fed. Cir. 1991) involves patents with a priority date in the mid-1980's. Thus, the science at the time of *Amgen* was more than a decade prior to the science of the instant specification. The facts are also distinguishable in that Amgen was denied a patent, because it was unable to specify which analogs had the desired biological properties; thus there was an issue with making and using the claimed invention. *Amgen*, at 1027. Applicants provide numerous species of acyltransferases and a means of determining whether it has acyl transfer ability. Accordingly, the claims of the instant application are enabled and distinguishable from the facts in *Amgen*.

The Office rejects claims 7 and 8 as allegedly unenabled, because the claims are broadly drawn to encompass "an enormous number of polynucleotides encoding proteins that lacks 70% homology with the protein encoded by the polypeptides of" SEQ ID NOs: 32-37.

Applicants traverse the rejection. The number of members in a genus is not a valid basis on which to support a rejection of lack of enablement. Additionally, Claim 7 provides within its scope common structural and functional features. As a consequence, the number of polynucleotides encoding the common structural features is confined within this group. The group is then further set by the functional features of the polypeptides produced by the polynucleotide. The recited features define relationships among members of the claimed genus such that the scope of the claims corresponds to the scope of enablement in accordance with 35 U.S.C. § 112, first paragraph. Additionally, Applicants note that in order to support a rejection of enablement the Office must make specific findings of fact supported by the evidence as to the particular subject matter and then draw conclusions based on these findings of fact. M.P.E.P. § 2164.04. The Office has made allegations regarding the fact that the polypeptides can be those that have 30% or more identity. Identity of 30% or more amongst polypeptides not only is significant at the level of the sequence but also at the level of activity. Absent reasoning as to why this assertion lacks objective truth with regard to acyltransferases specifically, Applicants respectfully submit that a *prima facie* case of lack of enablement has not been adduced. In view of these arguments, Applicants respectfully request withdrawal of the rejection as to claims 7 and 8.

Claims 5-6 depend from rejected claim 7. The Office asserts that the claims are rejected for lack of enablement because (1) the hybridizing conditions recited in the claims fail to specify wash time, and (2) the hybridizing property of a nucleic acid cannot be used to predict the functional activity of the nucleic acid. Applicants disagree with the Office's arguments. First, the Office has issued numerous patents wherein recited hybridizing conditions fail to provide wash times within the claims. *See* for example claim 1 of U.S. Patent No. 6,949,693 (issued September 27, 2005) and claim 1 of U.S. Patent No. 6,878,859 (issued April 12, 2005 listing Primary Examiner Amy Nelson). Thus, Applicants assert that lack of recitation as to wash times does not render the claims unenabled. Additionally, Applicants note that the example of U.S. Patent No. 6,878,859 recites a plant with a specific feature in addition to the hybridizing language. Thus, Applicants submit that the language as presented in the claims is acceptable language, the use of which does not render the claims as lacking a sufficient enabling disclosure.

Claim 28 stands rejected as lacking enablement for allegedly not providing evidence "that the hybridizing property of a polynucleotide is sufficient for a skilled artisan to predict the function of the polynucleotide." Page 9, Office Action. Applicant respectfully disagree.

As discussed above, hybridization language is accepted language before the Office, as exemplified by some of the above-referenced U.S. Patents. Moreover, the Customer Partnership meetings for Group 1600 has discussed the use of hybridization language for such claims. The Group does not require that the skilled artisan predict the function of the polynucleotide based on the property of hybridization alone.

Thus for all the reasons cited above, the rejection for lack of enablement as to claims 2, 3, 5-12, 20, 22-25, and 27-41 should be withdrawn, and the claims allowed.

5. Claim Rejections – 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 2-3, 5-12, 20, 22-25, and 27-41 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants maintain traversal of the rejection as to these claims. Applicants direct the Examiner's attention to another presentation of SPE Remy Yucel, Ph.D. entitled "Percent Identity and the Written Description Requirement of 35 U.S.C. § 112, first paragraph." In that presentation, Dr. Yucel asserts that "[i]f a skilled artisan would have understood the inventor to be **in possession** of the **claimed** invention at the time of filing, *even if every nuance of the claim is not explicitly described in the specification*, then the requirement for an adequate written description is met." To determine this, one must weight factual considerations including (1) level of skill and knowledge in the art, (2) complete or partial structure, (3) physical and/or chemical properties, (4) functional characteristics, (5) correlation between structure and function, and (6) method of making. *Id.*

As argued above, the level of skill at filing had increased over the time period discussing in either the *Genentech* or *Amgen* cases. Additionally, Applicants provide 6 complete nucleic acid sequence and 6 complete polypeptide sequences from different plant species. Applicants also provide the functional characteristics of the polypeptides, namely that they are acyltransferases. Finally, Applicants provide methods of making the various acyltransferases as well as methods of identifying additional acyltransferases. Applicants further point out that by providing the different sequences of a class of polypeptides with a known activity (*i.e.*, an acyltransferase) and when weighing the factual considerations enumerated above, this would fall into a genus of acyltransferases meeting the written description requirement as discussed in Dr. Yucel's examples.

Applicants point out that SEQ ID NO: 21 and 22 could potentially bind to polynucleotides encoding proteins other than acyltransferases is irrelevant as discussed in

Section 4 *supra*. These sequences are highly conserved among acyltransferases. Additionally, it would not have been difficult at the time to determine whether a particular polypeptide encoded by a polynucleotide isolated in the manner taught encoded an a polypeptide with acyltransferase function.

With regard to the hybridization stringency of 5X SSC or 2X SSC at 50°C, we note that again, although this condition is not high stringency, again any sequence identified would also have to have the property of being an acyl transferase. This property is readily determinable, unlike the facts sets forth in *Amgen* discussed *supra*. Therefore, the fact that Applicants recite a moderate stringency condition in the claims and/or use SEQ ID NOS: 21 or 22 to probe does not negate the additional characteristic that the identified polynucleotide encode an acyltransferase.

Thus for at least the reasons above, and the reasons previously made of record, Applicants submit that there is sufficient written description for the claims. Accordingly the rejection for lack of written description as to claims 2-3, 5-12, 20, 22-25, and 27-41 should be withdrawn and the claims allowed.

CONCLUSION

In view of the foregoing, Applicants respectfully request the entry of the amendments to place the application in condition for allowance.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above or in the attached papers, such an extension is requested and the fee should also be charged to our Deposit Account.

If any matters remain outstanding, the Examiner is invited to contact the undersigned representative regarding this matter.

Respectfully submitted,
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